



MOLBIO DIAGNOSTICS PRIVATE LIMITED
ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

Mfg. Lic. No.: MFG/IVD/2019/000003

Date: 12/05/2021

Doc ID: COA/TP/ATM063

Brand Name: Trueprep[®] AUTO Transport Medium for Swab Specimen Pack			
Generic name: Medium for collection, Decontamination and Transport of Swab Specimen for Trueprep[®] AUTO			
Lot No.: ATM063	Mfg Date: 2021-05	Exp Date: 2023-04	A.R. No.: B-ATM-063
Pack size: 50T, 20T, 5T		Storage Temperature: 2°C to 40°C	

PRECAUTION: Refer Safety Data Sheet and follow instructions for use.

Sr. No.	Components in each kit	Specification	Observation
A	Contents in the carton (Trueprep [®] AUTO Transport Medium for Swab Specimen Pack)	(Present (P)/ Not Present (NP))	
1	Transport Medium	Present	Present


Performance on Truelab [®] micro PCR Analyzers					
Sr. No.	Control	Specification (Ct Values)		Test Lot (Ct Values)	
1	Specificity Tests	Test	IC	Test	IC
Negative Control					
1	Negative COVID-19	ND	IC should be detected	ND	24.6
2	Negative COVID-19			ND	25.0
3	Negative COVID-19			ND	25.6
Positive Control					
4	Positive COVID-19	Test and IC should be detected		27.11	24.8
5	Positive COVID-19	Test and IC should be detected		27.0	24.01
6	Positive COVID-19	Test and IC should be detected		27.14	23.6

*Ct- Cycle threshold

*IC- Internal Control

*ND- Not Detected

MANUFACTURING RECORDS ARE VERIFIED, CHECKED AND PRODUCT IS MANUFACTURED AS PER THE MASTER FORMULA, SAMPLES TESTED AND LOT IS RELEASED FOR SALE.


QUALITY CONTROL
Name: Dr. Praveen Kumar
Designation: QC Head

Molbio Diagnostics Private Limited

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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1Z0